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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/311,720	05/14/1999	GREGORY M. GLENN	PM254809	1614

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EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/311,720	Applicant(s) Glenn et al.
	Examiner G. R. Ewoldt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *7/10/01, and 11/05/01*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-116* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Applicants' amendment, filed 7/10/01, has necessitated a new restriction requirement. Note that said amendment has rendered a number of claims nonsensical, including independent Claim 1, Claim 37, Claims 41-43, etc.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-46, 55-111, and 115-116, drawn to a method for transcutaneous immunization to a pathogen comprising administering a polynucleotide encoding an antigen, and an adjuvant, classified in Class 424, subclasses 184.1 and 278.1 and Class 514, subclass 44.

II. Claims 1-46, 55-111, and 115-116, drawn to a method for transcutaneous immunization to a pathogen comprising administering an antigen, and a polynucleotide encoding an adjuvant, classified in Class 424, subclasses 184.1 and 278.1 and Class 514, subclass 44.

III. Claims 1-46, 55-111, and 115-116, drawn to a method for transcutaneous immunization to a pathogen comprising administering a polynucleotide encoding an antigen, and a polynucleotide encoding an adjuvant, classified in Class 424, subclasses 184.1 and 278.1 and Class 514, subclass 44.

IV. Claims 1-25, 44-49, 53-86, 90, 102-108, 110, and 115-116, drawn to a method for transcutaneous immunization to an autoantigen or allergy comprising administering a polynucleotide encoding an antigen, and an adjuvant, classified in Class 424, subclasses 184.1 and 278.1 and Class 514, subclass 44.

V. Claims 1-25, 44-49, 53-86, 90, 102-108, 110, and 115-116, drawn to a method for transcutaneous immunization to an autoantigen or allergy comprising administering an antigen, and a polynucleotide encoding an adjuvant, classified in Class 424, subclasses 184.1 and 278.1 and Class 514, subclass 44.

VI. Claims 1-25, 44-49, 53-86, 90, 102-108, 110, and 115-116, drawn to a method for transcutaneous immunization to an autoantigen or allergy comprising administering a polynucleotide encoding an antigen, and a polynucleotide encoding an adjuvant, classified in Class 514, subclass 44.

VII. Claims 1-25, 44-46, 50-52, 55-86, 90, 102-108, 110, and 115-116, drawn to a method for transcutaneous immunization to a tumor comprising administering a polynucleotide encoding an antigen, and an adjuvant, classified in Class 424, subclasses 184.1 and 278.1 and Class 514, subclass 44.

VIII. Claims 1-25, 44-46, 50-52, 55-86, 90, 102-108, 110, and 115-116, drawn to a method for transcutaneous immunization to a tumor comprising administering an antigen, and a polynucleotide encoding an adjuvant, classified in Class 424, subclasses 184.1 and 278.1 and Class 514, subclass 44.

IX. Claims 1-25, 44-46, 50-52, 55-86, 90, 102-108, 110, and 115-116, drawn to a method for transcutaneous immunization to a tumor comprising administering a polynucleotide encoding an antigen, and a polynucleotide encoding an adjuvant, classified in Class 514, subclass 44.

X. Claims 112-114, drawn to a method of introducing a polynucleotide into a skin cell, classified in Class 514, subclass 44.

The inventions are distinct, each from the other because:

3. Groups I-X are different methods. These inventions require different reagents, acting through different process steps, and have different endpoints. Therefore they are patentably distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Irrespective of whichever Group Applicant should elect, Applicant is further required under 35 U.S.C. § 121 to:

1) Elect a **specific** adjuvant,

2) List all Claims readable thereon including those subsequently added. Currently Claims 1-61 and 73-116 are generic.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Different adjuvants, such as CpG motifs and various chemokines, have different chemical properties and induce different types of immune responses. Therefore, the species of Groups I-X are independent and patentable over one another.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
January 9, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600